UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,196	02/21/2006	Pullabhatla Srinivas	U015822-7	8085

140 7590 09/04/2009

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
DEES, NIKKI H	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
09/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,196	SRINIVAS ET AL.	
	Examiner	Art Unit	
	Nikki H. Dees	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9 and 11-16* is/are pending in the application.

4a) Of the above claim(s) *15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed June 4, 2009, has been entered. Claims 1-5, 7-9, and 11-16 are currently pending in the Application. Claims 15 and 16 are withdrawn from consideration as being to drawn to a non-elected invention. Claims 6 and 10 have been cancelled. The previous 112 rejections of claims 1, 4 and 5 have been withdrawn in view of the amendments to claims 1, 4, and 5. The previous 112 rejections of claims 6 and 10 have been withdrawn in view of the cancellation of claims 6 and 10.

Election/Restrictions

2. Newly submitted claims 15 and 16 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 15 is to a product-by-process and claim 16 is to a method using the product of claim 15. As the 2-acetyl-1-pyrroline is known to be made stable by processes other than the encapsulation method of claim 1; the product does not require the specific sequence of steps of the method. The product can be prepared by other method as shown by Buttery et al (4522838); thus, the inventions are considered to be distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15 and 16 are withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. The word "labile" occurs only once in the instant specification, wherein it is stated that the instant method provides stability to a labile aroma chemical. This is not considered sufficient support for claims to a non-labile flavorant.

6. Further regarding claim 12, the cited phraseology clearly signifies a "negative" or "exclusionary" limitation for which the applicants have no support in the original disclosure. Negative limitations in a claim which do not appear in the specification as filed introduce new concepts and violate the description requirement of 35 USC 112, first paragraph, *Ex Parte Grasselli, Suresh, and Miller*, 231 USPQ 393, 394 (Bd. Pat. App. and Inter. 1983); 783 F. 2d 453.

The insertion of the above phraseology as described above positively excludes a salt of 2-acetyl-1-pyrroline, however, there is no support in the present specification for such exclusions. While the present specification is silent with respect to the use of salts of 2-acetyl-1-pyrroline other than in the prior art, is noted that as stated in MPEP 2173.05(i), the "mere absence of a positive recitation is not the basis for an exclusion."

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1 and 12 claim a "non-labile" flavorant. While Applicant has cited numerous occurrences of "labile" in patent claims, the presence of the word "labile" in claims of patents has no relation to the instant claims and whether the terminology is supported in the instant specification. As the term "non-labile" does not occur in the instant specification, its meaning in the instant claims is considered to be indefinite.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-5, 7, 9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partanen et al. (Partanen, R. Ahro, M., Hakala, M., Kallio, H., Forssell, P. 2002. Microencapsulation of caraway extract in β-cyclodextrin and modified starches. Eur. Food Res. Technol. Vol. 214. pp. 242-247) in view of Buttery et al. (4,522,838) and Wright (Wright, J. 2002. "Creating and Formulating Flavors." Food Flavour Technology. Ed. A. J. Taylor. CRC Press. pp. 1-26).

12. Partanen et al. teach a method for encapsulating caraway extract. The extract is added to a solution containing a starch which is an emulsifying starch. Gum arabic (gum acacia) is also used. The mixture was homogenized for 3 minutes (Emulsification of caraway extract, p. 243). The solution was then spray dried at 200°C inlet temp and 80°C outlet temp (Spray-drying of caraway extract emulsions, p. 243).

13. Partanen et al. are silent as to the method being used with 2-acetyl-1-pyrroline. They are also silent as to using the specific emulsifiers of claim 5 and the spray drying conditions of claim 9.

14. Buttery et al. teach 2-acetyl-1-pyrroline for use as a food flavoring (Abstract). They state that the 2-acetyl-1-pyrroline may be combined with carriers including starch for addition to foodstuffs (col. 2 lines 54-64). Buttery et al. go on to teach that 2-acetyl-1-pyrroline is soluble, and stable, in both ethanol and water, but the pure compound degrades (col. 3 lines 20-24).

15. The combination of Partanen et al. and Buttery et al. is silent as to spray drying conditions for 2-acetyl-1-pyrroline.

16. Wright teaches that it is common to spray-dry flavors to provide the flavors with improved stability (pp. 15-16). He also teaches that the processing conditions should be set for each flavor (p. 17).

17. As shown by Buttery et al., the pure compound of 2-acetyl-1-pyrroline is not stable and degrades; it needs to be dissolved or combined with other material for stability. Partanen et al. teach encapsulation of flavorings to stabilize them. Thus, it would have been obvious to use the method of Partanen et al. to stabilize the compound of Buttery et al. in order that it may be more storage stable. As to the new limitation of forming " a non-labile flavorant", the combination of the references teaches encapsulating of the compound. Thus, the property of " non-labile flavorant" is inherently present. The ratio of 2-acetyl-1-pyrroline to binder could have been adjusted by one of ordinary skill with no more than routine experimentation in order to result in a suitably stable dried flavor.

18. Further, one of ordinary skill in the art at the time the invention was made would have been able to optimize the spray-drying conditions for the flavor 2-acetyl-1-pyrroline with nothing more than routine experimentation, as is taught by Wright. The spray-dried flavor would have been expected to have improved resistance to oxidative degradation. As all of the flavor, the additional components, and spray-drying were known in the art at the time the invention was made, one of ordinary skill would have been able to combine the elements to provide the predictable result of a spray-dried 2-acetyl-1-pyrroline without undue experimentation and with the reasonable expectation of a suitable preserved flavor molecule.

19. Regarding claims 5,14, Partanen et al. teach their composition as emulsions to be spray dried (Emulsification of caraway extract, p. 243). As the prior art teaches their composition in the form of an emulsion, one of ordinary skill would have found it obvious to use known emulsifiers to stabilize the emulsion. It would have been within the skill of one in the art to determine the amount of emulsifier needed to form the proper emulsion. This can readily be determined through routine experimentation. The emulsifiers claimed by Applicant are well-known and widely used in the art; therefore, their use to stabilize the emulsion of Partanen et al. would have been considered obvious to one of ordinary skill at the time the invention was made. Undue experimentation would not have been required to incorporate the emulsifier, and there would have been a reasonable expectation that it would have functioned as expected to stabilize the emulsion.

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Partanen et al. (Partanen, R. Ahro, M., Hakala, M., Kallio, H., Forssell, P. 2002. Microencapsulation of caraway extract in β-cyclodextrin and modified starches. Eur. Food Res. Technol. Vol. 214. pp. 242-247) in view of Buttery et al. (4,522,838) and Gasser et al. (4,073,961).

21. The combination of Partanen et al. in view of Buttery et al. teaches a process for stabilizing 2-acetyl-1-pyrroline as detailed above.

22. The combination is silent as to vacuum shelf drying of the composition.

23. Gasser et al. teach the drying of a bouillon flavor base using a vacuum drying cabinet (vacuum shelf dryer) (Example 1).

24. One of ordinary skill in the art at the time the invention was made would have recognized that vacuum shelf drying was commonly known in the art of flavor preparation. It would have been obvious to substitute vacuum shelf drying for spray drying as both methods were known in the art for drying food additives. No more than routine optimization would have been required to select the temperature and vacuum for the drying of the composition. The final product would have been expected to be suitably dried and stabilized.

25. Claims 1-5, 7, 9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leshik (4,307,117) in view of Buttery et al. (4,522,838) and Wright (Wright, J. 2002. "Creating and Formulating Flavors." Food Flavour Technology. Ed. A. J. Taylor. CRC Press. pp. 1-26).

26. Leshik teaches a method for stabilizing a colorant. The method comprises dissolving water soluble components in water and homogenizing (col. 3 lines 50-55). The water soluble components include film forming encapsulents, including water soluble starches, modified starches, and gum arabic (gum acacia) (col. 4 lines 7-12). An emulsifier is added to form a good dispersion. Preferred emulsifiers include polysorbate 60 and polysorbate 80 (col. 4 lines 36-40). Leshik further teaches "[T]here are no numerical ranges of universal application for either the amount of water-soluble film-forming encapsulant or the dispersant, as these will depend on the specific

materials, processing conditions, and end use requirements." (col. 4 lines 47-51). The mixture is then spray dried and used to color food products (Abstract).

27. Leshik is silent as to his method being used with 2-acetyl-1-pyrroline. He is also silent as to using spray drying conditions as claimed.

28. Buttery et al. teach 2-acetyl-1-pyrroline for use as a food flavoring (Abstract). They state that the 2-acetyl-1-pyrroline may be combined with carriers including starch for addition to foodstuffs (col. 2 lines 54-64). Buttery et al. go on to teach that 2-acetyl-1-pyrroline is soluble, and stable, in both ethanol and water, but the pure compound degrades (col. 3 lines 20-24).

29. The combination of Leshik and Buttery et al. is silent as to spray drying conditions for 2-acetyl-1-pyrroline.

30. Wright teaches that it is common to spray-dry flavors to provide the flavors with improved stability (pp. 15-16). He also teaches that the processing conditions should be set for each flavor (p. 17).

31. As shown by Buttery et al., the pure compound of 2-acetyl-1-pyrroline is not stable and degrades; it needs to be dissolved or combined with other material for stability. Leshik teaches the encapsulation of flavorings to stabilize them. Thus, it would have been obvious to use the method of Leshik to stabilize the compound of Buttery et al. in order that it may be more storage stable. As to the new limitation of forming " a non-labile flavorant", the combination of the references teaches encapsulating of the compound. Thus, the property of " non-labile flavorant" is inherently present. The ratio of 2-acetyl-1-pyrroline to binder could have been adjusted

by one of ordinary skill with no more than routine experimentation in order to result in a suitably stable dried flavor. As to the amount of emulsifier in claim 14, it would have been within the skill of one in the art to determine the amount of emulsifier needed to form the proper emulsion. This can readily be determined through routine experimentation.

32. Further, one of ordinary skill in the art at the time the invention was made would have been able to optimize the spray-drying conditions for the flavor 2-acetyl-1-pyrroline with nothing more than routine experimentation, as is taught by Wright. The spray-dried flavor would have been expected to have improved resistance to oxidative degradation. As all of the flavor, the additional components, and spray-drying were known in the art at the time the invention was made, one of ordinary skill would have been able to combine the elements to provide the predictable result of a spray-dried 2-acetyl-1-pyrroline without undue experimentation and with the reasonable expectation of a suitable preserved flavor molecule.

33. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leshik (4,307,117) in view of Buttery et al. (4,522,838) and Gasser et al. (4,073,961).

34. The combination of Leshik in view of Buttery et al. teaches a process for stabilizing 2-acetyl-1-pyrroline as detailed above.

35. The combination is silent as to vacuum shelf drying of the composition.

36. Gasser et al. teach the drying of a bouillon flavor base using a vacuum drying cabinet (vacuum shelf dryer) (Example 1).

37. One of ordinary skill in the art at the time the invention was made would have recognized that vacuum shelf drying was commonly known in the art of flavor preparation. It would have been obvious to substitute vacuum shelf drying for spray drying as both methods were known in the art for drying food additives. No more than routine optimization would have been required to select the temperature and vacuum for the drying of the composition. The final product would have been expected to be suitably dried and stabilized.

Response to Arguments

38. Applicant's arguments filed June 4, 2009, have been fully considered but they are not persuasive.

39. Applicant argues (Remarks, pp. 6-7) that the age of the references of Buttery and Leshik indicates that the process of the instant claims was not an obvious solution to a problem known in the art.

40. In response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

41. As Buttery teaches that 2-acetyl-1-pyrroline (APR) may be combined with solid vehicles or carriers before addition to foodstuffs, the method of the instant claims where

the flavoring is combined with a binders to be provided in a stable form for addition to foodstuffs is considered an obvious modification of the prior art. Buttery et al. were concerned with providing an essentially pure form of APR, while Applicant's method requires only a small amount of APR relative to the amount of binder present in the composition. Therefore, concerns about stability would clearly be much different than those of providing the essentially pure compound of the prior art.

42. Applicant argues (Remarks, p. 7) that the stability provided by encapsulation would not be expected to make the flavor chemical non-labile.

43. As the word "labile" appears in Applicant's specification only once, and nowhere is it taught that the flavor produced is considered "non-labile," the process claimed by Applicant is considered to be an encapsulation process that imparts stability to a flavor chemical known in the art to be unstable. As encapsulation is a process well-known to be used in combination with flavors in order to stabilize them e.g. for storage stability or extended release in foodstuffs, the specific steps of the process claimed by Applicant's are considered to be obtainable through no more than routine experimentation by one of ordinary skill in the art. As encapsulation is known to provide stability to chemicals, there is no evidence of unexpected results obtained by Applicant's process.

Conclusion

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. D./
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794